ForPatients
by Roche

Impaired hepatic function Healthy Volunteers

A Multiple-Center, Open-Label, Non-Randomized Study to Investigate The Effect of Various Degrees of Hepatic Impairment on The Pharmacokinetics of A Single Intravenous Dose of RO7223280

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	BP43792

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A study to investigate the effect of various degrees of liver damage on the processing by the body of a single dose of RO7223280 given through the vein

F. Hoffmann-La Roche
Sponsor

Phase I
Phase

BP43792
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18-75 years	Yes

Background and study aims

Antibiotic-resistant bacterial infections are an urgent global threat to public health. Antibiotic resistance happens when germs like bacteria and fungi develop the ability to defeat the drugs designed to kill them. Acinetobacter baumannii is one such bacteria against which new antibiotics are required. RO7223280 is being developed for the possible treatment of such infections. RO7223280 selectively kills Acinetobacter and inhibits an essential bacterial process not targeted by currently available antibiotics. RO7223280 prevents the growth of Acinetobacter carrying all known antibiotic resistance mechanisms tested to date, including resistance to a drug called carbapenem (carbapenem-resistant Acinetobacter baumannii; CRAB). Based on these favorable properties, RO7223280 is being developed for the treatment of hospital-acquired (nosocomial) bacterial lung infection (pneumonia; HABP), a lung infection that develops in a person who is on a ventilator (ventilator-associated bacterial pneumonia; VABP), and

bloodstream infection due to CRAB. Health authorities have not yet approved RO7223280 for the treatment of bacterial infection due to Acinetobacter baumannii. The main aim of this study is to measure how much of the drug gets into the bloodstream and how long it takes the body to get rid of it when given to participants with normal liver function or differing levels of liver problems (impairment). In addition, the safety and tolerability of the RO7223280 and any side effects that occur will also be evaluated.

Who can participate?

Male and female participants between 18 and 75 years of age with normal liver function or differing levels of liver impairment

What does the study involve?

Participants will need to be a part of this study for about 5 weeks. The study will include the following parts:

1. A screening part of up to 28 days to check the eligibility of participants to take part in the study

2. A dosing/treatment period of up to 1 day. Participants with normal liver function and mild, moderate, or severe liver damage will receive a single dose of RO7223280, through the vein (IV infusion) on Day 1. Participants will have to get admitted to the clinic 1 day before receiving the treatment and will have to stay in the clinic for 3 days after receiving the treatment.

3. A follow-up part during which participants will return to the clinic for a follow-up visit 7 (±2) days following drug administration.

What are the possible benefits and risks of participating?

Participants' health may or may not improve in this study, but the information that is learned may help other people suffering from similar conditions in the future. Participants will receive monetary compensation for taking part in the study.

Participants may have side effects from RO7223280, or procedures used in this study. These can be mild to severe and even life-threatening, and they can vary from person to person. There may be side effects that are not known at this time. The potential side effects associated with RO7223280, and other procedures are listed below:

Risks associated with RO7223280:

1. Allergic reaction: itching, difficulty breathing, rash, drop in blood pressure, and in rare cases life-threatening allergic reaction.

2. Potential side effects: chills, fever, nausea, high or low blood pressure, fast heart rate, itching, flushing, shortness of breath, headache.

Risks associated with study procedures:

1. Blood sampling: drawing blood can cause pain, bruising, or infection where the needle is inserted. Some people experience dizziness, fainting, or upset stomach when their blood is drawn.

2. Electrocardiograms (ECG): ECG patches may cause a skin reaction such as redness or itching. Participants may also experience localized skin discomforts and/or hair loss associated with the placement of ECG leads.

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Participants who become pregnant or are currently breastfeeding cannot take part in this study.